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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/776,914	02/11/2004	Gerhard Schmid	SCHMID, G. ET AL.-1	3052

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MAEWALL, SNIGDHA	
ART UNIT	**PAPER NUMBER**
1615	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/776,914	SCHMID ET AL.	
	Examiner	Art Unit	
	Snigdha Maewall	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *06/20/2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11,14 and 15* is/are pending in the application.

4a) Of the above claim(s) *12 and 13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11,14 and 15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Summary

1. Receipt of Applicant's Arguments/Remarks filed on 06/20/2007 is acknowledged.

Claims 7, 10 and 15 have been Amended by the Applicants. Claims 12-13 have been cancelled by the Applicant. Accordingly, claims **1-11 and 14-15** are pending in this application and claims **1-11 and 14-15** will be examined on the merits.

2. The rejections made under 35 USC 112.1 and 35 USC 112.2 in the Office Action dated 04/09/2007have been withdrawn in view of Applicant's Amendments to the claims.

The following are new rejections as necessitated by the Applicants Amendments.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1-11 and 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Artisa et al. (US Pg Pub No. 2005/0019375 A1) in view of Suzuki et

al. (JP 6-094912) and further in view of Mayer Davis (Diabetes care volume 24, April 2001) and International Diabetes federation (Fact Sheet Impaired Glucose tolerance).

Artisa et al. discloses a composition and method that relate to fat containing consumable food products comprising .alpha.-cyclodextrin. The food products have reduced levels of bioavailable fat but have substantially the same fat, cholesterol and caloric content as a like food without .alpha.-cyclodextrin. The invention also relates to methods for reducing the bioavailability of fats in fat containing food products without reducing caloric intake as determined by bomb calorimetry and to methods for increasing high density lipoproteins in a subject and reducing or controlling weight by administering the food products comprising alpha cyclodextrin (abstract).
Artisa et al. discloses that the total cyclodextrin in the foods is less than about 9-10% w/w, preferably less than about 6%, and more preferably below 3% w/w, and particularly in the case of fat containing consumable farinaceous food products, the amount of total cyclodextrin is below about 3% w/w. The .alpha.-cyclodextrin composition that is used in the products and methods is a substantially pure .alpha.-cyclodextrin comprising at least about 95% .alpha.-cyclodextrin, preferably at least 98% .alpha.-cyclodextrin . Artisa et al. further discloses that the consumable products comprising alpha- cyclodextrin are a dairy food product, a prepared vegetable product, or a prepared meat product, e.g. a prepared beef, lamb, pork, poultry or seafood food product. The consumable food products are suitable for consumption by mammals,
e.g., mice, rats, cats, dogs and humans but preferably humans (page 4, [0023]).
The consumable food product is a diet food that inhibits the rate of weight gain,

promotes weight loss and provides other health benefits (page 4, paragraph [0024]). Artisa et al. further disclose that by ingesting alpha.-cyclodextrin in an appropriate amount with a fat-containing meal, or shortly before or after ingesting a fat-containing meal, a subject may complex the ingested fat and inhibit its absorption by the body (page 5, paragraph [0028]).

Artisa et al. does not specifically teach reducing the glycemic index of the food.

Suzuki discloses that alpha- cyclodextrin and the composition with alpha –cyclodextrin as the major component have specific biological effects. One of such effects is that of a low calorie carbohydrate, having effective actions of body weight gain suppression and body weight reduction and the second effect is suppression of blood triglyceride concentration at a low level by inhibiting liver triglyceride accumulation.(page 6, paragraph 2). Alpha cyclodextrin and its composition helps in treatment of obesity and is important in treatment of hypertriglycemia, arteriosclerosis and triglyceride acuumulative fatty liver (page 6, paragraph2). Suzuki discloses administering alpha-cyclodextrin containing composition to a subject and the alpha-cyclodextrin is present in the composition in amounts of 10-40% (Examples 1-5 and page 7 of the translation); the alpha-cyclodextrin can be used in the form of powder, granules, aqueous solution (page 7). Suzuki discloses that alpha-cyclodextrin has an inhibitory effect on body weight gain and is administered food at 12-25g/kg body weight for the total cyclodextrin or at 6-13g/kg body weight for the alpha-cyclodextrin (page 4). Therefore it is apparent that alpha-cyclodextrin inherently reduces the glycemic index of the food comprising alpha cyclodextrin.

Mayer-Davis teaches that lifestyle changes can result in improved glucose tolerance among individuals at high risk for developing type 2 diabetes. A reduced-fat diet may result in sustained improvements in glycemic status after 5 years. [first paragraph].

The International Diabetes Federation teaches that weight loss can reduce insulin resistance and make the insulin produced more effective at controlling bloodglucose.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify food having a glycemic index by reducing the glycemic index of the food comprising alpha-cyclodextrin and administering the same to an individual or individuals with impaired glucose tolerance because Artisa et al. teaches reduction of fat by using alpha-cyclodextrin,

Suzuki teaches weight gain inhibitory effects due to alpha-cyclodextrin and its relationship in reducing glucose concentration, Mayer teaches that reduced fat diet may result in improvements in glycemic status and International Federation teaches controlling blood glucose with low fat diet.

The skilled artisan would have been motivated to do so with an expectation of success because it is known in the art that alpha-cyclodextrin helps in reducing fat which in turn helps in improvements in glycemic improvements. With regards to various concentration, it is the position of the examiner that optimization of such parameter would have been within the purview of a skilled artisan at the time the invention was made absent evidence to the contrary. Applicant is reminded that where the general conditions of the claims are met, burden is shitted to applicant to provide a patentable

distinction. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. See In re Aller, 220 F.2d 454 105 USPQ 233,235 (CCPA 1955).

5. Claims 1-11 and 14-15 are rejected under 35 U.S.C. 103(b) as being unpatentable over Suzuki et al. (JP 6-094912) in view of Mayer Davis (Diabetes care volume 24, April 2001) and International Diabetes federation (Fact Sheet Impaired Glucose tolerance).

The teachings of Mayer Davis (Diabetes care volume 24, April 2001) and International Diabetes federation (Fact Sheet Impaired Glucose tolerance) have been discussed above.

Suzuki discloses that alpha- cyclodextrin and the composition with alpha –cyclodextrin as the major component have specific biological effects. One of such effects is that of a low calorie carbohydrate, having effective actions of body weight gain suppression and body weight reduction and the second effect is suppression of blood triglyceride concentration at a low level by inhibiting liver triglyceride accumulation.(page 6, paragraph 2). Alpha cyclodextrin and its composition helps in treatment of obesity and is important in treatment of hypertriglycemia, arteriosclerosis and triglyceride acuumulative fatty liver (page 6, paragraph2). Suzuki discloses administering alpha-cyclodextrin containing composition to a subject and the alpha-cyclodextrin is present in the composition in amounts of 10-40% (Examples 1-5 and page 7 of the translation); the

alpha-cyclodextrin can be used in the form of powder, granules, aqueous solution (page 7). Suzuki discloses that alpha-cyclodextrin has an inhibitory effect on body weight gain and is administered food at 12-25g/kg body weight for the total cyclodextrin or at 6-13g/kg body weight for the alpha-cyclodextrin (page 4). Therefore it is apparent that alpha-cyclodextrin inherently reduces the glycemic index of the food comprising alpha cyclodextrin.

It would have been obvious to one of ordinary skilled in the art at the time the invention was made to modify food having a glycemic index by reducing the glycemic index of the food comprising alpha-cyclodextrin and administering the same to an individual or individuals with impaired glucose tolerance because Suzuki teaches weight gain inhibitory effects due to alpha-cyclodextrin and its relationship in reducing glucose concentration, Mayer teaches that reduced fat diet may result in improvements in glycemic status and International Federation teaches controlling blood glucose with low fat diet. The skilled artisan would have been motivated to do so with an expectation of success because it is known in the art that alpha-cyclodextrin helps in reducing fat which in turn helps in improvements in glycemic improvements. With regards to various concentration, it is the position of the examiner that optimization of such parameter would have been within the purview of a skilled artisan at the time the invention was made absent evidence to the contrary. Applicant is reminded that where the general conditions of the claims are met, burden is shitted to applicant to provide a patentable distinction. Where the general conditions of a claim are disclosed in the prior art, it is not

inventive to discover the optimum or workable ranges by routine experimentation. See In re Aller, 220 F.2d 454 105 USPQ 233,235 (CCPA 1955).

Response to Arguments

6. Applicant's arguments with respect to claims 1-15 have been considered but are moot in view of the new ground(s) of rejection.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Snigdha Maewall whose telephone number is (571)-272-6197.

The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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1615

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